

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2011 has been entered.

### ***Previous Rejections***

Applicants' arguments, filed 28 February 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-3, 5-13, 15, and 17-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benz et al. (US Patent Application Publication 2003/0162905) in view of Shalaby et al. (US Patent Application Publication 2003/0199964) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3<sup>rd</sup> Edition, Chapter 7, pages 189-225). The**

Applicant argues that the rejection is not proper. The Applicant states that the references do not teach or suggest the significance of the presence of the vinyl acetate in the polymers. As stated in the instant specification, the polarity of the polymers plays a role in the release kinetics and Tg. The Applicant also argues that there are a significantly large number of combinations of biopolymers and terpolymers, and thus a significantly large number of polymer blends that could result from the cited references. And the rejection is not proper in view of *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, because there are not a small number of options. The Applicant further argues that the rejection was made by impermissible hindsight reconstruction, with various elements from the claims being extracted from the prior art and combined without an articulated reason or rationale beyond stating that these elements exist.

The Examiner acknowledges the presented arguments, but does not consider them persuasive. The Examiner notes that the references do not discuss the role of the vinyl acetate for affecting the release profile due to its polarity. However, the postulated effect between the vinyl acetate (and its polarity) and the release profile is not considered sufficient to overcome the rejection. The claims recite a polymer with this monomer present, and there is no requirement that the prior art teach the speculative properties of all of the elements, nor do the references need to suggest including the element for the same reason as put forth in the specification. See MPEP 2144(IV).

The argument regarding the number of options is also not considered persuasive. The Applicant cites case law (which itself discusses KSR) that relates to an obviousness rejection based on an “obvious to try” rationale. The instant rejection was not based on such a rationale.

The Examiner also does not agree that the rejection is based on improper hindsight reconstruction. The rejection did not merely present the instantly claimed elements as known and conclude the invention was obvious without providing a rationale. A reason was provided for using the vinyl acetate block, namely that Benz taught that this polymeric block provides for adhesion of a polymeric coating to a stent, and Shalaby et al. teaches that it is desirable for the coating to adhere to the stent. And the reason to combine the polymeric materials was based on case law (and as discussed in MPEP 2144.06), which was also cited to support the reasoning for the modification.

**Claims 14 and 22-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Benz et al. (US Patent Application Publication 2003/0162905), Shalaby et al. (US Patent Application Publication 2003/0199964), and Van Krevelen (“Properties of Polymers,” 1990, Elsevier, 3<sup>rd</sup> Edition, Chapter 7, pages 189-225), as applied to claim 13 above, and further in view of Sirhan et al. (US Patent Application Publication 2002/0082677).** The Applicant presented no arguments specifically directed to this rejection, and for the reasons discussed above, the arguments against the rejection of claim 13 are not considered persuasive.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 8,088,404.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims recite a polymer blend with an additional homopolymer present. However, the two polymers, the active agent, and the inclusion of these ingredients as a coating on a stent

(which are the elements recited by the instant claims) are all recited by the copending claims as well. Thus, the conflicting claims recite a stent that falls within the scope of the device recited by the instant claims.

Applicant is advised to use form PTO/SB/25 (07-09), which is reproduced at page 1400-120 in Revision 7 (July 2008) of the 8<sup>th</sup> edition of the MPEP when filing any Terminal Disclaimer. This will prevent any delays due to omissions from the language set forth therein.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullede whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday from 5:30 am - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Gulledge/  
Primary Examiner, Art Unit 1612